



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Illum *et al.*)
)
Serial No. 09/841,228)
)
Filed: 21 October 1999)
)
Examiner: S L Howard)
)
Art Unit: 1615)
)
For: A NASAL DRUG)
DELIVERY COMPOSITION)

DECLARATION OF LISBETH ILLUM

Commissioner for Patents
Washington, D.C. 20231

I, Lisbeth Illum, declare that

1. I hold degrees of M.Pharm (1972), PhD (1978) and DSc (1988) from the Royal Danish School of Pharmacy. I am the Chief Scientific Advisor for West Pharmaceutical Services, Drug Delivery and Clinical Research Centre Ltd., a company specialising in drug delivery systems. I am also associated with Nottingham University as a Special Professor.
2. My research expertise is in the area of novel drug delivery systems for peptide and protein drugs. I have studied the mechanisms of delivery of drugs using transmucosal routes. My other research efforts include the development of colloidal carrier systems for site specific delivery of drugs.
3. I was involved in the conception and development of the invention described and claimed in the above-identified patent application and I am named as an inventor in the above-identified patent application.
4. I have read and understand the office action dated 10 April 2002. My understanding is that a basis of the rejection of the above identified Illum *et al.* application is that the Examiner considers that the subject matter of claims 1 to 11 is obvious over the disclosure of

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US-A-6,096,728 (Collins *et al.*) in view of US-A-5,811,425 (Woods *et al.*).

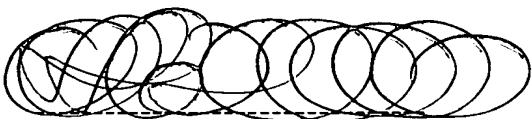
5. In particular, I understand that the Examiner considers that it would have been obvious to produce compositions adapted for nasal administration such as those claimed because Collins *et al.* teaches that drugs of the type defined in the claimed compositions can be formulated as emulsions and because Woods *et al.* teaches that such drugs can be formulated as emulsions that comprise a hydroxylated oil. The Examiner further states that the oil-in-water emulsion and the water-in-oil emulsion are "encompassed" in a generic teaching of an emulsion in the prior art.
6. I have read and understand the teaching of both of Collins *et al.* and Woods *et al.* and I do not agree with the Examiner's basis for the obviousness rejection.
7. A mere general disclosure of an emulsion, as provided in Collins *et al.* and Woods *et al.* is not the same as a specific disclosure of a specific type of emulsion. This disclosure of a generic emulsion would not provide the skilled person with any teaching as to the specific type of emulsion that is used in the compositions of the invention as claimed.
8. An emulsion is a colloidal suspension of one liquid in another. A person of ordinary skill in the art is knowledgeable as to the different types of emulsions and oil-in-water emulsions are simply one example of these. Evidence of this is provided on page 323 of "Remington: the Science and Practice of Pharmacy" (A R Gennaro, 20th Edition) (copy attached). Thus, in my opinion, the general disclosure of an emulsion in Collins *et al.* and in Woods *et al.* is not the same as a disclosure of an oil-in-water emulsion.
9. Even if Collins *et al.* did provide a specific teaching of an oil-in-water emulsion, which it does not, there are many different types of oils that could be used to form an oil-in-water emulsion. The general disclosure in Collins *et al.* provides no incentive to select a hydroxylated oil for inclusion in such an emulsion.
10. In my opinion, the teaching in Woods *et al.* provides no incentive to select a hydroxylated oil from the long list of possible diluents and emulsifiers in Woods *et al.* for use in compositions comprising an oil-in-water emulsion that are adapted for nasal administration.
11. In my opinion, neither Collins *et al.* nor Woods *et al.* provides any teaching as to what level of drug should be included in the oil phase

of an oil-in-water emulsion. Thus, neither of these documents provides any teaching to provide a composition adapted for nasal administration comprising an oil-in-water emulsion wherein more than 50% by weight of the drug is dissolved in the oil phase.

12. In summary, in my opinion, it would not have been obvious to the person of ordinary skill in the art reading Collins *et al.* in view of Woods *et al.* at the priority date of the present application to produce the claimed compositions.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Codes and that such wilful false statements may jeopardise the validity of the application and of any patent issuing thereon.

Declarant further saith not.

A handwritten signature consisting of a series of overlapping loops, resembling a stylized 'L' or a cursive 'Lisbeth'.

LISBETH ILLUM

Date 6.9.02